APR 2 8 2004

K040340

510(k) SUMMARY

Submitter Personal Products Company Division of McNeil-PPC Inc.
199 Grandview Road
Skillman, New Jersey 08558-9418

Contact Person Marylou P. Carlson
Mgr. Regulatory Affairs
(908) 904-3709 phone (908) 904-3748 fax

Date Prepared February 02, 2004

Proprietary Name K-Y® Brand
WARMING UltraGEL Personal Lubricant

Common Name Personal Lubricant

Classification Name Condom: 21CFR § 884.5300 Product Code 85HIS
Patient Lubricant: 21CFR 880.6375 Product Code MMS

Predicate Device K-Y® Brand Warming LIQUID Personal Lubricant

Description of Device
K-Y® Brand WARMING UltraGEL is a non-sterile, clear, non-staining, non-greasy, water soluble gel for use as a personal lubricant. This product imparts a gentle warming sensation when applied to the genitalia. This product was designed to meet a customer need for an intimate lubricant that does not feel cold when applied. K-Y® Brand Warming UltraGEL can reduce friction during sexual intercourse thereby enhancing sexual intimacy. It is compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according the standards as defined by ASTM D 3492. K-Y® Brand WARMING UltraGel is not a contraceptive nor spermicide.

Intended Use
K-Y® Brand WARMING UltraGEL is intended as personal lubricant to be used with or without a condom.

The lubricous nature of this product helps to supplement the body's own natural lubricating fluids, thereby relieving friction to help enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal, anal or penile tissues for purpose of lubrication, and moisturization and is compatible with latex condoms. K-Y® Brand WARMING UltraGEL has the additional benefit of imparting a warming sensation when applied to the genital area.

Regulatory Status
Per 21CFR, 880.6375, Patient lubricant is defined as a Class I medical device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Patient lubricants are not exempt from 510(k) clearance. Additionally when used as an accessory to a condom, (a Class II medical device) the lubricant is considered, by FDA, as a Class II Medical Device requiring 510(k) clearance.

510(k) SUMMARY (continued)

Technological Characteristics
The K-Y® Brand WARMING UltraGEL Personal Lubricant formula is proprietary. The product, has no exceptional technological characteristics and consists mainly of safe water-soluble GRAS status ingredients somewhat similar to other K-Y® Brand personal lubricants currently on the market.

Substantial Equivalence
K-Y® Brand WARMING UltraGEL Personal Lubricant has been shown, in laboratory tests, to be substantially equivalent to the currently marketed K-Y® Brand Warming LIQUID Personal Lubricant. Both devices have the same intended use with a variation in formula ingredients. The gentle warming technology is the special feature of the K-Y® Brand WARMING lubricant products.

Preclinical Testing of Formulation
Biocompatibility safety studies according to International Standard ISO 10993 and General Program Memorandum G95-1 on K-Y® Brand WARMING UltraGEL were conducted by an outside laboratory, in compliance with Good Laboratory Practices (GLPs). Results form these studies, demonstrated that K-Y® Brand WARMING UltraGEL was not considered to be a contact sensitizing agent, nor was it associated with systemic toxicity.

Human Clinical Testing
In a Human Repeated Insult Patch Test (Modified Draize Procedure), this product was compared to the currently marketed K-Y® Warming LIQUID for its potential for contact sensitization. Under the conditions of this test no evidence of contact sensitization was elicited.

A Consumer Perception Study evaluated both male and female subjects' experience of warmth with a single application of the product to their genitals during an on-site visit. Overall 80.00% of the participants rated the product as Excellent, Very Good or Good for "*Warms on Contact*" and 95.00% for "*Does not feel cold when applied*" There were no adverse events observed or reported during the course of this study.

An In-Home Consumer Use Study was conducted to evaluate both consumer perception of warmth during sexual activity as well as the tolerability of the product through vulvo/vaginal speculum examination prior and post product use. Consented female subjects received gynecological examinations at baseline and following the last coital episode. The study was conducted in compliance with 21CFR Part 812 for Investigational Device Exemption and 21CFR Parts 50 and 56. Efficacy results for this study concluded that in 245 reported responses, 91.67% were positive for "*Warms on Contact*" and 85.01% were positive for "*Enhances Intimacy*" and 8.6% responded positively to "*experienced discomfort*". Additionally, after two weeks of home use, (with a minimal of two sexual intercourse encounters) there were no serious adverse events reported. Gynecological examinations detected only one instance of mottled irregular erythema of the inner thigh area at baseline, which was not present at the return visit. It was concluded that the product did not cause irritation as determined by final gynecological examination.

Preclinical and Clinical testing have provided scientific evidence that this product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

Ms. Marylou (Panico) Carlson
Manager Regulatory Affairs
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558

Re: K040340
Trade/Device Name: K-Y® Brand Warming UltraGel Personal Lubricant
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient lubricant
Regulation Name: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 80 MMS and 85 HIS
Dated: February 6, 2004
Received: February 11, 2004

Dear Ms. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K040340**

Device Name: **K-Y® Brand Warming Ultra Gel**

Indications For Use: **Personal Lubricant**
For vaginal/penile and condom application during sexual intimacy

Prescription Use _____ AND/OR Over-The-Counter Use _X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Krysan

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040340